Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/509,275	**Applicant(s)** BRORS ET AL.	
	Examiner Bradley L. Sisson	**Art Unit** 1634	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 May 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-15,17 and 18*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Bradley L. Sisson/
Primary Examiner
Art Unit: 1634

Continuation of 11. does NOT place the application in condition for allowance because: At page 3 of the response received 29 May 2008, applicant directs attention to MPEP 2107.01, section C, and also asserts:

"Applicant submits that mRNA quantification, like gas chromatographs, screening assays, and nucleotide sequencing techniques that "have a clear, specific and unquestionable utility", because they are useful in analyzing amounts of mRNA molecules, thereby facilitating the acquisition of important information and insight."

The above argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection of claims under 35 USC 101 and 112, first paragraph. As an initial matter, it is noted that the claims are not drawn to a device such as chromatographs. It is further noted that the method is not drawn to the screening of any compound or to the sequencing of any nucleic acid.

Contrary to applicant's assertions, the standard to be applied is not whether there is "a clear, specific and unquestionable utility," but rather, a "specific, credible, and substantial" asserted utility or a "well-established utility." As set forth at page 6 of the Utility Guidelines: "An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a 'real world' context of use ..." However, in the instant case, the claimed method is not directed to the quantification of any molecule that has any asserted correlation with any condition, be it a disease or not. Even if a given RNA molecule was quantified, the skilled artisan would be required to carry out further research to identify or reasonably confirm any real world use for not only the RNA molecule but also for the information gleaned from the claimed assay. Given this fact pattern, the claimed method may well meet the specific and credible prongs of the three-prong test, but it fails the "substantial" utility test.

At page 3 of the response, argument is presented that the claimed "method is useful regardless of whether the quantified mRNA is associated with an expressed sequence tag (EST) or whether the function of the protein it encodes is known or unknown." This argument would be persuasive if the claimed method were directed to the analysis of mRNAs, or the corresponding ESTs that were associated with a gene, or encoded protein, whose function was known. However, the claimed method is not directed to the analysis of any mRNA, or associated EST, gene, or protein that is known, or for which a reasonable association has been made.

Argument is presented that the invention falls under MPEP 2107.01 C "Research Tools." As noted above, the claimed method does not relate to any device or to any of the identified methods. The claimed method does, however, more closely parallel example (C) found under MPEP 2107.01 B:

(C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility.

The Office does recognize that there are many RNA molecules, as well as corresponding cDNA molecules, that do meet the test for utility; however, the claimed method is not directed to any of these categories of RNA (or cDNA) molecules.

At page 4 of the response applicant makes assertions as to what one of skill in the art would have recognized. This argument has been fully considered and has not been found persuasive. Attention is directed to MPEP 2145.

"Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art. The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration."

At page 4 of the response, applicant directs attention to the response of 19 November 2007 and to the publications (Exhibit A and B) that were submitted. It is noted that at page 10 of the 19 November 2007 response, applicant asserts in part: "microarrays are known in the art to be useful for measuring levels of useful RNAs including endogenous transcript." The claimed method is not directed to microarrays or to their usefulness. Indeed, microarrays and even the claimed method would have utility if it were to be directed to "useful RNAs;" however, as noted above, the claimed method is not directed to any RNA that has utility under 35 USC 101. The two publications (Zhang et al., Genome Research, November 15 1999, pp. 681-688; and Gray et al., Carcinogenesis, 2000, Vol. 21, No. 3, pp. 443-452) disclose methods that are not commensurate in scope with the claimed method. It is noted, for example, in Zhang et al., specific genes are identified and evaluated. And in Gray et al., an analysis of gene copy number is done on breast cancer cell lines using a known gene profile for a specific chromosome. In contrast, the claimed method recites no gene, no chromosome, and no condition.

For the above reasons, and in the absence of convincing evidence to the contrary, the rejection of claims under 35 USC 101, and under 35 USC 112, first paragraph, are maintained.